Reply

The additional perspectives supplied by Peter Harris and the other committee members of EUROSTAR in their letter regarding my editorial[1] are most welcome and should convince the readers of the Journal of Vascular Surgery that they have acted responsibly in reporting the results of their registry.

I think they should be aware that, from previous conversations, I support EUROSTAR's objectives and continue to look forward, both as a vascular surgeon and an editor, to the objective perspectives their reports are regularly bringing to this field. I do not see the EUROSTAR investigators as part of the problem I was addressing but as potential leaders in developing solutions. North American trialists could well take a page from their book. Anything that will produce the wider dissemination of objective outcomes in this fast changing field, including the prompt reporting of significant adverse events, is welcomed, as is support of these efforts by industry, *as long as it is without inappropriate superimposed controls.*

One point worthy of further comment is *the importance of reporting device-specific data.* The EUROSTAR committee believes that some "caution is justified with regard to direct head-to-head comparison." That may be true, but lumped data of experiences with multiple devices are of limited value if the data are not stratified for device. Caution indeed might be needed if device-specific groups are not also compared with regard to case severity and the factors known to affect outcome to be sure apparent performance differences are real. That has to do with proper reporting practices. Limited early data from the learning curves of new devices can be withheld from such comparisons until there are sufficient numbers to avoid type II errors. I know the EUROSTAR has been uncomfortable with this limitation on reporting device-specific data and am pleased to see it changing.

A second important issue is *what is the appropriate middle ground between "premature allegations of device failure" and significantly delayed disclosure,* on which the EUROSTAR investigators have clearly tried to tread. They fear that the former extreme could expose researchers to claims from manufacturers for compensation for commercial damages and that professional advice may well be appropriate before entering into research contracts. This point is well taken and is one of the aspects dealt with by myself and Dr Johnston in a broader commentary on the potential problems with industry-supported clinical research, which will soon be published in this journal, so I will not comment further on it, except to say that actions strictly motivated by concern for patient safety would seem unlikely to be held liable. One is more likely to be held liable for not protecting patient safety.

In regard to specific problems not being identified by device, it was stated that "we considered that the company itself had the primary responsibility to disclose this information to the professional world." The companies do have this responsibility, but clinical investigators have a responsibility to the proper reporting of trial data. Also, patient safety is their prime responsibility and it should be a central consideration during the joint discussions, which are invariably held between the principal investigators and the company representatives when such problems are first discovered. Charges of "premature allegations of device failure" are unlikely to arise from such discussions. The company may ask for discretion while more information is quickly gathered, but some additional action seems to be appropriate if multiple device-related complications of the same kind have been observed, such as ending the enrollment of patients in a trial or ending the marketing of the device so that it will not be implanted in other patients before the likely cause and seriousness of the complication is satisfactorily determined. Such cautious actions should not "unnecessarily alarm" patients who already have the device, another of their concerns, but it might protect patients who could be future candidates for the device. Interestingly, the low-risk limb of the US Vanguard trial was stopped at about the time the information on the six fabric erosions was disclosed, with the declaration of full enrollment.

Thirdly, I presume that it is from a sense of fairness that the authors also defend Boston Scientific Corporation, but that is unnecessary. I was eventually able to get in touch with one of their representatives after the case report of a fabric erosion in a Vanguard endograft, on manuscript revision, revealed that there were actually six cases of erosion. Charles Pierson of Boston Scientific Corporation kindly supplied me with much additional perspective, some of which I was able to insert at the galley proof stage of my editorial. So, I am now privy to much of the information in your letter. The issue remains whether such letters to its customers fulfills a company's responsibilities regarding the safety of the ultimate customer of this device, the patient. Also at issue is how adequately such communications between the company and those who insert its devices will inform the vascular surgeons

in the community, to whom a patient with abdominal aortic aneurysm may present and who must decide between proceeding with open repair or referring the patient to one of the endograft centers, and if so which one. I am not convinced that this amounts to being "both timely and effective in alerting the vascular community," as you claim. Thus, I am not willing to alter one of my closing statements that such disclosure "does not diminish the awareness gap that exists for much of the vascular community."

I doubt that the EUROSTAR steering committee and I differ significantly philosophically or in our goal to bring full and complete information on these new abdominal aortic aneurysm endograft devices to the vascular community as quickly as possible. If some of the examples selected in my editorial directed toward this goal have been taken personally, as an attack on EUROSTAR, I hope my reply reassures them that this was certainly not the intention.

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REFERENCES

1. Rutherford RB. Problems with the dissemination of up-to-date information on the results of endograft repair for abdominal aortic aneurysm. J Vasc Surg 1999;29:1167-9.

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